DSHS Laboratory Senate Bill 80 Report SAO Audit Report #11-001

August 2012 Texas Department of State Health Services



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Executive Summary

Introduction

Texas's three public health laboratories, operated by the Department of State Health Services (DSHS), are located in Austin, San Antonio, and Harlingen. The variety of testing performed by these laboratories includes: newborn screening and genetic tests, microbiological tests, clinical chemistry tests, sexually transmitted disease screening, select agent testing in support of homeland security activities, and other public health related tests such as environmental testing, food safety testing, and rabies testing.

In September 2010, the State Auditor's Office (SAO) issued a report on the public health laboratories that cited findings related to billing, revenue collections, financial record-keeping, and information security practices at DSHS's public health laboratories. The audit included recommendations for changes to practice and policy at the public health laboratories relating to these findings.

Background

Senate Bill (S.B.) 80 by Senator Nelson was passed in 2011 during the 82nd Regular Session of the Texas Legislature. This statute requires DSHS to adopt and implement the recommendations described in the SAO's September 2010 report, "An Audit Report of the Department of State Health Services' Public Health Laboratories," and sets forth the actions that DSHS is required to undertake. Additionally S.B. 80 requires DSHS to submit a report to the governor, the lieutenant governor, the speaker of the House of Representatives, and the Legislature on DSHS's progress in implementing the provisions not later than September 1, 2012.

Update on SB 80/SAO Audit Recommendation Implementation Activities

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Recommendation	SAO Date	Actual Date	Comment
1-A. The Department Had Not Billed for Most Tests Conducted at the South Texas Laboratory since July 2008.		SAO Completion Target: 03/31/11 Actual Completion Date: 04/29/11	
Resume all billing for tests at South Texas Laboratory (STL).	03/31/11	04/12/11	Completed.
Establish a process to review and bill for un-billed tests at STL.	03/31/11	01/18/11	Completed.
Establish and implement a process to ensure Medicaid-eligible services are billed on time.	02/01/11	01/18/11	Completed.
Pursue becoming a Medicaid provider.	03/31/11	04/29/11	Completed.
1-B. The Department Did Not Ensure That It Billed for All Tests Conducted at the Austin Laboratory.		SAO Completion Target: 12/31/10 Actual Completion Date: 11/30/2011	
Perform and document periodic reconciliations between the billing application and the laboratories' information management applications. It should also follow up on and correct all errors identified during those reconciliations.	12/31/10	11/30/11	Completed.
Ensure all testing records are properly recorded and retained.	12/31/10	12/31/10	Completed.
1-C. The Department Did Not Have a Reasonable Cost Allocation Methodology on Which to Base Its Fee Schedules.		SAO Completion Target: 09/30/11 Actual Completion Date: In Process; New Fees scheduled to be effective 09/01/12.	
Develop, document, and implement procedures for setting fees for laboratory services.	12/31/10	01/04/11	Completed.
Retain all documentation related to fee setting.	09/30/11	08/31/11	Completed.
Ensure that the department uses a documented methodology to set all fees for laboratory services.	09/30/11	08/29/11	Completed.
Analyze the department's costs and update its fee schedule as needed.	09/30/11	10/07/11	Completed.
1-D. The Department Did Not Report Accounts Receivable for Its Laboratories or Have Procedures for Writing Off Uncollectible Receivables.		SAO Completion Target: 05/31/11 Actual Completion Date: 12/30/10	
Report accounts receivable balances for uncollected billings for the laboratory at fiscal year-end.	11/20/10	09/30/10	Completed.

Recommendation	SAO Date	Actual Date	Comment
Develop policies and procedures for disposing of uncollectable receivables and writing off receivables considered uncollectable.	10/31/10	11/15/10	Completed.
Develop policies and procedures for informing medical test submitters of delinquent accounts.	05/31/11	12/30/10	Completed.
1-E. The Department Properly Processed Payments Received for Austin Laboratory Services; However, the Department Did Not Accurately Credit Accounts for Prepayments Received at the South Texas Laboratory.		SAO Completion Target: 03/31/11 Actual Completion Date: 03/31/11	
Implement policies and procedures for tracking submitter billing statement disputes.	03/31/11	03/31/11	Completed.
Continue the implementation of the process to address the submitter billing disputes.	Not specified	02/08/11	Completed.
2-A. The Department's Laboratories Have Detailed Policies and Procedures for the Processing of Specimens.		SAO Completion Target: Not specified. Actual Completion Date: 09/01/10	
Address statements within the report which could call into question the integrity of the testing conducted in the laboratory. No formal recommendations provided but the DSHS response to the report indicated that the laboratory has procedures to validate test data and documentation is available to verify that the laboratory adheres to those procedures.	Not specified	09/01/10	Completed.
2-B. The Department Does Not Have Controls for Accounting for the Laboratories' Inventories.		SAO Completion Target: 08/31/11 Actual Completion Date: 08/31/11.	
Develop and implement and document a comprehensive inventory tracking process for the department's laboratories.	08/31/11	08/31/11	Completed.
Ensure that the department's laboratories can quantify the amounts of inventory on hand.	08/31/11	08/31/11	Completed.
2-C. The Department Did Not Report Consumable Inventory in Its Annual Financial Reports as Required.		SAO Completion Target: 11/20/10 Actual Completion Date: 09/07/10.	
The department should report the amounts of inventory on hand in its laboratories at the end of each fiscal year.	11/20/10	09/07/10	Inventory submitted for FY10 (on 09/07/2010) and for FY11; will be conducted annually.

Recommendation SAO Date 2-D. The Department Does Not Have a Process to Ensure That Specimens Are Protected and Processed in a Timely Manner in the Event of an Emergency or Disaster.		Actual Date Comment SAO Completion Target: 08/31/11 Actual Completion Date: Ongoing		
Establish a timeline for completing the Continuity of Operations Plan for the department's laboratories.	01/31/11	02/10/11	Completed.	
Implement procedures to ensure that the laboratories have a plan in place to protect specimens submitted for testing, testing supplies, and laboratory equipment.	08/31/11	Ongoing	The Power Outage policy has been approved and added to the COOP document. Arrangements with other labs in case of a disaster are being pursued, as appropriate to the testing.	
2-E. The Department Did Not Conduct Inspections of Hazardous Materials Storage as Required.		SAO Completion Target: 09/30/10 Actual Completion Date: 09/30/10		
The department should implement a process to ensure that inspections of the laboratories' hazardous materials storage building are conducted weekly.	09/30/10	09/30/10	Completed.	
2-F. The Department Lacks Controls to Safeguard Items.	nt Lacks Controls to Safeguard Inventory		SAO Completion Target: 12/01/10 Actual Completion Date: 06/17/11	
Develop a process to track access to the laboratories' inventory storage building.	12/01/10	06/17/11	Completed.	
Enhance access controls over the laboratories' information management applications.	12/01/10	06/17/11	Completed.	
Chapter 3. The Department Does Not Have Adequate Controls or Provide Sufficient Oversight to Ensure that the Information in Its Testing and Billing Applications for Its Laboratories Is Complete or Accurate.		SAO Completion Target: 01/31/11 Actual Completion Date: 04/07/11		
Develop a process to ensure that the policies and procedures in place at the Department, including change management and acceptable use policies, are communicated and incorporated in the operations of the laboratory.	01/31/11	03/07/11	Completed.	
Develop a process to ensure that all software installations are properly authorized and reviewed prior to implementation.	01/31/11	02/18/11	Completed.	

Recommendation	SAO Date	Actual Date	Comment
Conduct a review of user access security to ensure that user access is appropriate and is based on each user's job roles and responsibilities.	01/31/11	02/17/11	Completed.
Implement a process to monitor and update user access to the department's information technology applications to ensure that access is appropriate and granted to only current employees.	01/31/11	03/01/11	Completed.
Review password controls over the laboratory information management applications to ensure that appropriate password policies have been established on the network and on each laboratory application.	01/31/11	03/10/11	Completed.
Develop and perform reconciliation procedures to ensure that records are complete and accurate prior to the transfer of data to the billing application.	01/31/11	04/07/11	Completed.

Conclusion

The DSHS laboratories provide a first line of defense in protecting the health and safety of the citizens of the State of Texas. With the direction and support of the Legislature, DSHS has worked to address each of the findings cited by the SAO and continues efforts to improve internal processes and achieve efficiencies by focusing on core public health services such as disease prevention, control and surveillance.

The DSHS Laboratories are committed to providing accurate, precise and timely test results for diagnostic and analytical functions for the assessment and surveillance of infectious, communicable, genetic and chronic diseases and environmental exposure.

Its role ranges from supporting state and national disaster preparedness plans, serving as the state's primary reference laboratory for the detection and diagnosis of unusual pathogens, ensuring the safety of the public food and water supply, to testing for low-incidence, high-risk diseases such as tuberculosis, rabies, botulism and plague. The services of the DSHS Laboratories are critical to the provision of public health services in Texas.

As a partner in safeguarding public health, DSHS is committed to stewardship of public resources and maintaining excellence in laboratory science testing services. DSHS appreciates the opportunity to share our progress and achievements in addressing these findings and wishes to recognize the efforts of the many dedicated, hard-working public servants who work every day in these public health laboratories to serve the needs of Texans.

Appendices

Appendix I

Chapter 1. The Department did not ensure that it issued bills and collected revenue in a timely manner and set fees in compliance with state statutes and rules.

Finding 1-a: The Department had not billed for most tests conducted at the South Texas Laboratory since July 2008.

Recommendations:

- Resume all billing for tests conducted at the South Texas Laboratory and review and address all unbilled activity as appropriate.
- Establish a process to review and bill for tests conducted at the South Texas Laboratory that have not been billed.
- Establish and implement a process to ensure Medicaid-eligible services are billed within the required time frame.
- Pursue obtaining provider status through the U.S. Centers for Medicaid and Medicare Services to become a Medicare provider.

Response to Finding 1-a: The South Texas Laboratory (STL) is now a Medicaid provider. All billing for tests performed at STL have resumed. DSHS has established a process to review and bill for un-billed tests at STL. DSHS has established and implemented a process to ensure Medicaid-eligible services are billed in a timely manner.

SAO Target Completion Date: 03/31/2011; Actual Completion Date: 04/29/2011.

Finding 1-b: The Department did not ensure that it billed for all tests conducted at the Austin Laboratory.

Recommendations:

- Perform and document periodic reconciliations between its billing application and the laboratories' information management applications to ensure that billings are complete and correct. It should also follow up on and correct all errors identified during those reconciliations.
- Ensure that all testing records are properly recorded and retained in a system with proper security controls, supervisory reviews and backup procedures.

Response to Finding 1-b: All testing records for tests at the Austin Laboratory are properly recorded and retained. A reconciliation process has been developed and is still being tested and improved. With the assistance of the billing system vendor, an automated identification of historical duplicate transactions was completed in November 2011.

SAO Target Completion Date: 12/31/2010; Actual Completion Date: Reconciliation of monthly records is an ongoing process and the process continues to be refined and improved to ensure any changes to the system will not result in duplicate transactions.

Finding 1-c: The Department did not have a reasonable cost allocation methodology on which to base its fee schedules.

Recommendations:

- Develop, document, and implement procedures for setting fees for laboratory services. This should include updating and implementing a documented cost allocation methodology that determines reasonable costs for specific types of tests.
- Retain all documentation related to fee setting, including the setting of fees for new tests and any modifications to existing test fees.
- Ensure that it uses a documented methodology to set all fees for laboratory services.
- Analyze its costs and update its fee schedules as needed so that the fees per test do not
 exceed the costs per test, as required by Texas Health and Safety Code, Section
 12.032(c).

Response to Finding 1-c: Procedures for setting fees for laboratory services using a documented cost allocation methodology have been develop, and implemented. This methodology and all related processes were developed with the assistance of a contracted Cost Accountant. All documentation related to laboratory fee setting is now documented and retained. The agency is in process of vetting the resulting calculated fees through the DSHS rules process which allows for public comment. The effective date for the new laboratory public fee schedule is September 1, 2012.

SAO Target Completion Date: 09/30/11; Actual Completion Date: 09/01/12.

Finding 1-d: The Department did not report accounts receivable for its laboratories or have procedures for writing off uncollectible receivables.

Recommendations:

- Report uncollected accounts receivable balances for its laboratories at the end of each fiscal year as required by the Comptroller of Public Accounts.
- Develop policies and procedures for disposing of uncollectible accounts receivable and writing off accounts receivable considered uncollectible in compliance with the Office of the Attorney General's requirements.
- Develop policies and procedures for informing laboratory test payors of delinquent accounts.

Response to Finding 1-d: Accounts receivable balances for uncollected billings for the laboratory at fiscal year-end was reported for FY2010 and FY2011. Policies and procedures for disposing of uncollectable receivables and writing off receivables considered uncollectable and for informing medical test submitters of delinquent accounts has been developed and is in place since 12/30/2010.

SAO Target Completion Date: 05/31/2011; Actual Completion Date: 12/30/2010.

Finding 1-e: The Department properly processed payments received for Austin Laboratory services; however, the department did not accurately credit accounts for pre-payments received at the South Texas Laboratory.

Recommendations:

- Implement policies and procedures for tracking submitter billing statement disputes.
- Continue the implementation of the process to address submitter billing disputes, including use of the separate form for submitters to use when submitting claims for the Texas Health Steps program.

Response to Finding 1-e: DSHS has continued the implementation of the process to address the submitter billing disputes. Uncollected accounts receivable balances were reported for FY 10 and FY11 as required by the Comptroller of Public Accounts. DSHS Billing Branch Internal Policy number 2011_10 has been developed, adopted and implemented to ensure these balances are reported annually.

In order to ensure procedures for disposing of uncollectable accounts receivable are in compliance with the Office of the Attorney General's requirements, DSHS Billing Branch Internal Policy number 2010_016 has been developed, adopted and implemented by the Billing Branch.

Additionally, in order to ensure the notification of laboratory customers of delinquent accounts, DSHS Billing Branch Internal Policy number 2010 015 has been developed, adopted and implemented by the Billing Branch.

SAO Target Completion Date: 03/31/2011; Actual Completion Date: 03/31/2011.

Finding 1-f: The Department has processes to manage selected appropriations in accordance with the General Appropriations Act.

No Recommendations.

Appendix II

Chapter 2. While the Department's Laboratories have detailed procedures for processing specimens submitted for testing, the Department lacks sufficient controls to safeguard and track the laboratories' inventories of testing supplies.

Finding 2-a: The Department's Laboratories have detailed policies and procedures for processing specimens.

No Recommendations.

Finding 2-b: The Department does not have controls for accounting for the laboratories' inventories.

Recommendations:

- Develop and implement a comprehensive inventory tracking process for its laboratories, including documented policies and procedures. This process should include regular inventory counts and reconciliations of inventory.
- Ensure that its laboratories can quantify the amounts of inventory on hand.

Response to Finding 2-b: The DSHS Laboratory developed, implemented, and documented a comprehensive inventory tracking process as of 08/31/2011. The laboratory can quantify the

amounts of inventory on hand and reported end of year inventory information for both FY2010 and FY2011.

SAO Target Completion Date: 08/31/2011; Actual Completion Date: 08/31/2011

Finding 2-c: The Department did not report consumable inventory in its annual financial reports as required.

Recommendation:

• Report the amounts of inventory on hand in its laboratories at the end of each fiscal year in its annual financial report as required.

Response to Finding 2-c: DSHS has developed procedures for accounting of inventory in the DSHS Laboratories. The inventory on hand at the end of the fiscal year was reported in the Department's Annual Financial Report and will be reported annually, as required.

SAO Target Completion Date: 11/20/2010; Actual Completion Date: 09/07/2010

Finding 2-d: The Department does not have a process to ensure that specimens are protected and processed in a timely manner in the event of an emergency or disaster.

Recommendations:

- Establish a timeline for completing the continuity of operations plan for its laboratories. This includes developing agreements to outsource critical operations as needed during an emergency.
- Implement procedures to ensure that the laboratories have a plan in place to protect specimens submitted for testing, testing supplies, and laboratory equipment in the event of an emergency.

Response to Finding 2-d: The DSHS Laboratory Continuity of Operations Plan (COOP) has been completed. Procedures have been implemented to ensure that the laboratories have a plan in place to protect specimens submitted for testing, testing supplies, and laboratory equipment.

Additionally, DSHS is in the process of entering into contracts/agreements to carry out that plan, as appropriate. An account with Quest Laboratories has been established which covers essential testing required by Clinical Chemistry and Microbiology and an agreement with the Lower Colorado River Authority (LCRA) has been executed for environmental testing. In addition, an agreement for Newborn Screening Program testing with the State of Florida is in process.

SAO Target Completion Date: 08/31/2011; Actual Completion Date: In process/Ongoing.

Finding 2-e: The Department did not conduct inspections of hazardous materials storage as required.

Recommendation:

• The Department should implement a process to ensure that inspections of the laboratories' hazardous materials storage building are conducted weekly as required by federal law.

Response to Finding 2-e: DSHS has implemented a process to ensure that inspections of the laboratories' hazardous materials storage building are conducted weekly. The process was established by developing and approving a Standard Operating Procedure (SOP) that provides details on who will conduct the weekly inspection when the Safety Officer is not available. These individuals have been trained on performing the inspections. Documentation of weekly inspections is maintained by the Safety Officer.

Additionally, electronic key card readers have been installed on each of the doors to rooms of the Hazardous Materials building that contain laboratory inventory. Entrance to these rooms is limited to the Laboratory Supply staff, Laboratory Building Coordinator, and the Safety Officer. Reports are available to document all access to these rooms.

SAO Target Completion Date: 09/30/2010; Actual Completion Date: 09/30/2010

Finding 2-f: The Department lacks controls to safeguard inventory items. Recommendations:

- Develop a process to track access to the laboratories' inventory storage buildings.
- Enhance access controls over the laboratories' information management applications.

Response to Finding 2-f: DSHS has now developed a process to track access to the laboratories' inventory storage; access is now controlled by way of installed electronic key card readers.

Access controls over the laboratories' information management applications has been enhanced by the addition of strengthened password functionality for the HealthPac (billing) system that complies with criteria established by the State of Texas for handling internal passwords.

Also, system Administrator access was removed from Non-IT users in the various laboratory information management systems (LIMS), and access to the server room was made limited to only authorized personnel with entry controlled by electronic key card readers.

SAO Target Completion Date: 12/01/2010; Actual Completion Date: 06/17/2011

Appendix III

Chapter 3. The Department does not have adequate controls or provide sufficient oversight to ensure that the information in its testing and billing applications for its laboratories is complete or accurate.

Recommendations:

- 1. Develop a process to ensure that the policies and procedures in place at the Department, including change management and acceptable use policies, are communicated and incorporated in the operations of the laboratories.
- 2. Develop a process to ensure that all software installations are properly authorized and reviewed prior to implementation, in accordance with the Department's information technology security policy.
- 3. Conduct a review of user access security to ensure that user access is appropriate and is based on each user's job roles and responsibilities.

- 4. Implement a process to monitor and update user access to the Department's information technology applications to ensure that access is appropriate and granted to only current employees.
- 5. Review password controls over the laboratory information management applications to ensure that appropriate password policies have been established on the network and on each laboratory application.
- 6. Develop and perform reconciliation procedures, such as a record total count, to ensure that records are complete and accurate prior to the transfer of data to the billing application.

Response to Finding Chapter 3: The DSHS Laboratory and IT Applications and Development group have established a Change Control Request Board for the review and approval of major changes to all DSHS laboratory information management systems (LIMS). Procedure was written to detail which changes must be reviewed by the board, and which changes may be approved by the Laboratory Unit Manager and IT Applications and Development Manager. Procedures were developed to address all recommendations of the SAO auditors, which are presented in the following table.

SharePoint path: Application Development >Shared Documents >SAO Temporary
Document Repository> All Documents

Recommendation 1)	pnp_Lab_CCRB_process v1.1.doc
Recommendation 2)	<pre>pnp_LIMS_Software_changes_process v1.1.doc</pre>
Recommendation 3)	<pre>pnp_LIMS_Software_changes_process v1.1.doc</pre>
Recommendation 4)	<pre>pnpHarvest_UserSecuritySetting_v1.0.doc</pre>
	pnpHarvest_UserRoles_Review_v1.0.doc
	pnpHealthPac_UserSettings_1.2.doc
	pnpLabWare_RolesDescription_SAO_v1.0.doc
	pnpLabWare_UserUpdates_v1.doc
	pnpSAO_MonitorUpdateUserAccess_LIMS_v1.8.doc
	WHL_PowerPath_User_Access v1.0.doc
	xlsHarvest_RolesAndFunctions_v1.0.xls
Recommendation 5)	SAO_LIMSPasswordConfigurations_1.1.doc
Recommendation 6)	Labworks_Billing_Process.doc
	Labworks_Billing_Reconciliation_Process.doc
	<pre>pnpHarvest_BillingReconciliationProcess_ATX_Manual_1.0.doc</pre>
	<pre>pnpHealthPac_ReconcileBillingAgainstLIMS_v1.4.doc</pre>
	<pre>pnpLabWare_BillingData_Oracle_STL_v4.doc</pre>
	<pre>pnpLabWare_BillingData_Oracle_v5.doc</pre>
	<pre>pnpLabWare_BillingData_Reconciliation_v1.1.doc</pre>
	ITG 3 0 Harvest AL Billing Reconciliation.doc
	ITG 4 0 PowerPath AL Billing Reconciliation.doc
	pnpNBS_NBS4Cards_BillingReconciliation_v1.0.doc